Proposed Registration Decision PRD2010-05

Acequinocyl

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Proposed Registration Decision for Acequinocyl

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing a renewal of the conditional registration for the sale and use of Acequinocyl Technical, Shuttle 15 SC Miticide and Kanemite 15 SC Miticide, containing the technical grade active ingredient acequinocyl, to control mites on ornamental, floral, foliage and nursery crops in greenhouses and shadehouses, and in field-grown ornamentals and pome fruit.

Acequinocyl Technical (Registration Number 28639), Shuttle 15 SC Miticide (Registration Number 28640) and Kanemite 15 SC Miticide (Registration Number 28641) were granted a conditional registration in Canada in 2007. The detailed review for Acequinocyl Technical, Shuttle 15 SC Miticide and Kanemite 15 SC Miticide can be found in Evaluation Report ERC2007-10, *Acequinocyl*. The original evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, as a condition of the original registrations, additional scientific information was requested from the applicant to be submitted by December 2008. In support of the request to renew the conditional registrations, a rationale for renewal of the registration in the absence of required data or information was provided. Based on a review of the submitted rationale, the request to renew the conditional registrations is granted until December 31, 2011. The requirement to submit additional scientific information as a condition of registration remains.

This overview describes the key points of the evaluation, while the Science Evaluation in ERC2007-10 provides detailed technical information on the human health, environmental and value assessments of acequinocyl, Shuttle 15 SC Miticide and Kanemite 15 SC Miticide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on acequinocyl, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on acequinocyl, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation in ERC2007-10.

What Is Acequinocyl?

Acequinocyl is a contact miticide that is applied to leaves to control specific mites. Acequinocyl can be applied in greenhouses and shadehouses on container-grown ornamental, floral, foliage and nursery crops as well as on field-grown ornamentals and pome fruit using ground application equipment. Acequinocyl inhibits electron transfer at the mitochondrial level in target mites and is effective against all immature life stages. It may have indirect effects on adults of some target pest species.

Health Considerations

Can Approved Uses of Acequinocyl Affect Human Health?

Acequinocyl is unlikely to affect your health when used according to the label directions.

People could be exposed to acequinocyl through diet (food and water) or when handling and applying the product. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only the uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when products containing acequinocyl are used according to the label directions.

Acequinocyl as well as Kanemite 15 SC Miticide and Shuttle 15 SC Miticide were of low toxicity to animals after a single dose administration, were not irritating to the skin or eyes and did not cause skin sensitization. Acequinocyl did not cause cancer in animals and was not genotoxic. There was also no indication that acequinocyl caused damage to the nervous system, and there were no effects on reproduction. The first sign of toxicity in animals given daily doses of acequinocyl over longer periods of time was disruption of the blood coagulation system, characterized by increased clotting time and internal hemorrhage. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When acequinocyl was given to pregnant animals, effects on the developing fetus were not observed, indicating that the fetus was not more sensitive to acequinocyl than the adult animal. Consequently, no extra protective measures were applied during the risk assessment.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that children in the one to two year old and three to five year old subpopulations, which would ingest the most acequinocyl relative to body weight, are expected to be exposed to less than 26% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from acequinocyl is not of concern for all population subgroups.

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using end-use products containing acequinocyl on pome fruit were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of ERC2007-10.

Workplace Risks From Handling Shuttle 15 SC Miticide and Kanemite 15 SC Miticide

Occupational risks are not of concern when Shuttle 15 SC Miticide and Kanemite 15 SC Miticide are used according to the label directions, which include protective measures.

Direct skin contact can occur when farmers and custom applicators mix, load or apply either Shuttle 15 SC Miticide or Kanemite 15 SC Miticide and when workers re-enter freshly treated fields, nurseries, greenhouses and shadehouses. Therefore, the label specifies that anyone mixing/loading Kanemite 15 SC Miticide must wear a long-sleeved shirt, long pants and gloves and that anyone applying Kanemite 15 SC Miticide must wear a long-sleeved shirt and long pants. The label for Shuttle 15 SC Miticide also specifies that anybody mixing/loading/applying the end-use product must wear a long-sleeved shirt, pants and gloves. The labels also require that workers do not enter treated areas for 12 hours after application. Taking into consideration these label statements, the number of applications and that occupational exposure is expected to be of short to medium duration for handlers and workers, risk to these individuals is not a concern.

For bystanders, the exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Acequinocyl Is Introduced Into the Environment?

Acequinocyl is toxic to freshwater and estuarine/marine invertebrates; therefore, label instructions are required to protect these organisms during pesticide application and handling. Aquatic buffer zones are required during application.

Acequinocyl enters the environment when used as a miticide on field-grown ornamentals and pome fruit trees as well as on nursery crops in greenhouses and shadehouses. Acequinocyl is non-persistent to slightly persistent in both soil and water. The major transformation products formed in soil and water are non-persistent to slightly persistent in soil and slightly persistent in water. Acequinocyl and its major transformation products are not expected to leach through the soil profile beyond 30 cm; therefore, they are not expected to enter ground water. Based on its low volatility (vapour pressure and Henry's law constant), acequinocyl residues are not expected in the air.

Acequinocyl presents a negligible risk to wild mammals, birds, earthworms, bees, beneficial arthropods, terrestrial plants, fish, amphibians and algae. However, it is expected to adversely affect aquatic invertebrates living in freshwater and estuarine/marine habitats adjacent to areas of application. Therefore, specific instructions to reduce spray drift to aquatic invertebrates are provided on the end-use product label.

Also, buffer zones of 1 to 35 metres (depending on timing of application) are required to protect nearby freshwater and estuarine/marine habitats from the effects of spray drift.

Value Considerations

What Is the Value of Acequinocyl?

Acequinocyl, a miticide, controls two-spotted spider mites and spruce spider mites on greenhouse and field grown ornamentals. When used on pome fruit, acequinocyl controls two-spotted spider mites and European red mites.

A single application of acequinocyl controls specific mites on ornamentals (greenhouse, shadehouse and field grown) and pome fruit. It is also compatible with current management practices and conventional crop production systems. Growers are familiar with the monitoring techniques to determine if and when applications are needed.

There are no miticides from the same class as acequinocyl currently registered for use on the listed crops; therefore, acequinocyl offers a new class of miticide for resistance-management purposes. When applied according to the label directions, acequinocyl is effective at controlling two-spotted spider mite, spruce spider mite and European red mite.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

Human Health

- On the Shuttle 15 SC Miticide and Kanemite 15 SC Miticide labels, the following text will appear: "Wear a long-sleeved shirt and long pants during all product handling activities. In addition, wear chemical-resistant gloves during mixing, loading, clean-up and repair activities."

Environment

- As Kanemite 15 SC Miticide is toxic to aquatic invertebrates, exposure of these organisms to spray drift should be minimized. Specific instructions to reduce spray drift are provided on the end-use product label.

- Kanemite 15 SC Miticide cannot be sprayed within 1 to 35 metres of sensitive aquatic habitats. The distance allowed depends on the timing of application (early verses late in the season).

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of ERC2007-10 or in the Section 12 Notice associated with the renewal of these conditional registrations. The applicant must submit the following information within the time frames indicated.

- **Environment**

  Identification of the unknown major transformation product in the phototransformation on soil study. Submission of this information to the PMRA must be made no later than December 1, 2011.

  An acute toxicity study and a chronic toxicity study using the major transformation product acequinocyl-OH (R1) with the freshwater invertebrate *Daphnia magna*. Submission of this information to the PMRA must be made no later than December 1, 2011.

  An acute toxicity study using the major transformation product, acequinocyl-OH (R1), with two estuarine/marine invertebrates: saltwater mysid and eastern oyster. Submission of this information to the PMRA must be made no later than December 1, 2011.

Next Steps

Before making a final registration decision on the applications to renew the conditional registration for acequinocyl, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on acequinocyl (based on the Science Evaluation in ERC2007-10). In addition, the test data referenced in ERC2007-10 will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

List of Abbreviations

cm	centimetres
MRL	maximum residue limit
PMRA	Pest Management Regulatory Agency
ppm	parts per million